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PATENT
Attorney Docket No. FJN-063

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

TECH CENTER 1600/2900

APPLICANT(S): Nakagawa et al.

SERIAL NO.: 09/051,670 GROUP NO.: 1647

FILING DATE: April 16, 1998 EXAMINER: Romeo, D.

TITLE: Novel DNA and Process for Preparing Protein Using DNA

Assistant Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

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\$180.00 OP

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 C.F.R. 1.311, and
 - the requisite Statement is below, **OR**
 - the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein, or
- (3) after the mailing date of a **final action** or **notice of allowance** but before the payment of the **issue fee**, **AND**

- the requisite Statement is below, AND
- the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

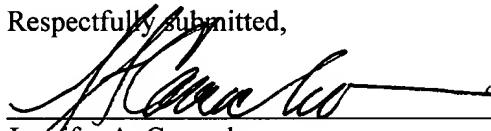
It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

STATEMENT

As required under 37 C.F.R. 1.97(e), Applicant(s), through the undersigned, hereby state either that [check the appropriate space only if either (2) or (3) is checked on the previous page and the Statement is required]:

- 1. Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application **not more than three months** prior to the filing of the Information Disclosure Statement; or
- 2. No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to **any individual** designated in 37 C.F.R. 1.56(c) **more than three months** prior to the filing of the Information Disclosure Statement.

Respectfully submitted,


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SHEET 1 OF 2

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| FORM PTO - 1449 INFORMATION DISCLOSURE STATEMENT | | ATTORNEY DOCKET NO.: FJN-063 APPLICANT(S): Nakagawa et al. SERIAL NO.: 09/051,670 FILING DATE: April 16, 1998 GROUP: 1647 |
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U.S. PATENT DOCUMENTS

| EXAM. INIT. | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB CLASS | FILING DATE IF APPROPRIATE |
|-------------|-----|-----------------|----------|------|-------|-----------|----------------------------|
| | A3 | 5,118,667 | 6/2/92 | | 514 | 12 | |
| | A4 | 5,393,739 | 2/28/95 | | 514 | 12 | |
| | A5 | 5,578,569 | 11/26/96 | | 514 | 12 | |
| | A6 | 5,599,708 | 2/4/97 | | 435 | 240.27 | |
| | A7 | 5,658,756 | 8/19/97 | | 435 | 69.1 | |
| | A8 | 5,843,678 | 12/1/98 | | 435 | 7.1 | |
| | A9 | 5,985,832 | 11/16/99 | | 514 | 12 | |
| | A10 | 6,017,729 | 1/25/00 | | 435 | 69.1 | |

FOREIGN PATENT DOCUMENTS

| EXAM. INIT. | | DOCUMENT NUMBER | DATE | COUNTRY CODE | CLASS | SUB CLASS | FILING DATE | ABSTRACT ONLY | ENGLISH LANG (Y/N) |
|-------------|----|-----------------|----------|--------------|---------|-----------|-------------|---------------|--------------------|
| | B4 | 0 514 130 A2 | | EP | A61K 37 | 02 | 05/12/92 | | Y |
| | B5 | 0 727 211 A1 | 08/21/96 | EP | A61K 31 | 50 | 2/7/96 | | Y |
| | B6 | 96/28546 | 9/19/96 | WO | C12N 15 | 00 | 3/15/95 | | Y |
| | B7 | 97/00317 | 1/3/97 | WO | C12N 15 | 11 | 6/4/96 | | Y |
| | B8 | 97/00318 | 1/3/97 | WO | C12N 15 | 11 | 6/7/95 | | Y |



OTHER ART, JOURNAL ARTICLES, ETC.

| EXAM. INIT. | OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication) |
|----------------|---|
| C9 | Anderson et al., "A homologue of the TNF receptor and its ligand enhance T-cell growth and dendritic-cell function", <u>Nature</u> , Vol. 390, November 13, 1997, pp. 175-179. |
| C10 | Chambers et al., "Generation of osteoclast-inductive and osteoclastogenic cell lines from the H-2btsA58 transgenic mouse," Proceed. of the National Acad. of Sciences of USA, vol. 90, June 1993, pgs. 5578-5582. |
| C11 | Chenu et al., "Transforming growth factor β inhibits formation of osteoclast-like cells in long-term human marrow cells," Proceed. of the National Acad. of Sciences of USA, vol. 85, August 1998, pgs. 5683-5687. |
| C12 | Fawthrop, F.W. et al., "The Effect of Transforming Growth Factor β on the Plasminogen Activator Activity of Normal Human Osteoblast-like Cells and a Human Osteosarcoma Cell Line MG-63" <u>J. Bone and Mineral Res.</u> 7(12):1363-1371 (1992) |
| C13 | Fenton, A. J. et al., "Long-Term Culture of Disaggregated Rat Osteoclasts: Inhibition of Bone Resorption and Reduction of Osteoclast-Like Cell Number by Calcitonin and PTHrP[107-139]" <u>J. Cellular Phys.</u> 155:1-7 (1993) |
| C14 | George et al., <u>Macromolecular Sequencing and Synthesis</u> , New York, 1998, pg. 127-149. |
| C15 | Goodwin et al., "Molecular cloning and expression of the type 1 and type 2 receptors for tumor necrosis factor," Database EMROD, EMBL Databases, Accession Number: M59378, June 28, 1991. |
| C16 | Gowen et al., "Preferential Inhibition of Cytokine-Stimulated Bone Resorption by Recombinant Interferon Gamma," <u>Journal of Bone and Mineral Research</u> , vol. 1, number 5, 1986, pgs. 469-474. |
| C17 | Hattersley et al., "Human Macrophage Colony-Stimulating Factor Inhibits Bone Resorption by Osteoclasts Disaggregated From Rat Bone," <u>Journal of Cellular Physiology</u> , vol. 137, number 1, October 1998, pgs. 199-203. |
| C18 | International Search Report for PCT/JP98/01728 |
| C19 | Kaji et al., "Insulin-like growth factor-I mediates osteoclast-like cell formation stimulated by parathyroid hormone", <u>Journal of Cellular Physiology</u> , Vol. 172, No. 1, July 10, 1997, pp. 55-62. |
| C20 | Kasono et al., "Inhibitory effect of interleukin-4 on osteoclast-like cell formation in mouse bone marrow culture," <u>Bone and Mineral</u> , vol. 21, 1993, pgs. 179-188. |
| C21 | Rieger et al., <u>Glossary of Genetics and Cytogenetics</u> , Springer-Verlag, Berlin Heidelberg New York, 1976, pg. 17. |
| C22 | Simonet et al., "Osteoprotegerin: a novel secreted protein involved in the regulation of bone density," <u>CELL</u> , vol. 89, April 18, 1997, pgs. 309-319. |
| C23 | Takada et al., "A simple method to assess osteoclast-mediated bone resorption using unfractionated bone cells," <u>Bone and Mineral</u> , vol. 17, 1992, pgs. 347-359. |
| C24 | Watanabe et al., "Interleukin-4 as a Potent Inhibitor of Bone Resorption," <u>Biochem. and Biophys. Research Comm.</u> , vol. 172, number 3, 1990, November 1990, pgs. 1035-1041. |
| C25 | Wong et al., "TRANCE is a novel ligand of the tumor necrosis factor receptor family that activates c-Jun N-terminal kinase in T cell", <u>J.Biol. Chem.</u> , Vol. 272, No. 40, October 28, 1997, pp. 24727-25408. |
| EXAMINER | DATE CONSIDERED |